DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two new animal drug applications (NADAs) and three abbreviated new animal drug applications (ANADAs) from Delmarva Pharmaceuticals, Inc., to Virbac AH, Inc.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *dnewkirk@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Delmarva Laboratories, Inc., 1500 Huguenot Rd., suite 106, Midlothian, VA 23113, has informed FDA that it has transferred ownership of, and all rights and interest in, the following two approved NADAs and three approved ANADAs to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137:

Application No.	21 CFR Section	Trade Name
NADA 065–492	520.88f	ROBAMOX V (amoxicillin trihydrate) Tablets
NADA 065–495	520.88b	ROBAMOX V (amoxicillin trihydrate)
ANADA 200–071	522.900	EUTHASOL Solution
ANADA 200–291	520.447	CLINSOL (clindamycin hydrochloride) Liquid
ANADA 200–316	520.446	CLINTABS (clindamycin hydrochloride) Tablets

Accordingly, the agency is amending the regulations in §§ 520.88b, 520.88f, 520.446, 520.447, and 522.900 to reflect the transfer of ownership.

Following these changes of sponsorship, Delmarva Laboratories, Inc., is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Delmarva Laboratories, Inc.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

Animal drugs.

■ Therefore, under the Federal Food, Drug and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing

the entry for ''Delmarva Laboratories, Inc.'' and in the table in paragraph (c)(2) by removing the entry for ''059079''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.88b [Amended]

■ 4. Section 520.88b *Amoxicillin trihydrate for oral suspension* is amended in paragraph (c) by removing ''059079'' and by adding in its place ''051311''.

§ 520.88f [Amended]

■ 5. Section 520.88f *Amoxicillin trihydrate tablets* is amended in paragraph (b) by removing ''059079'' and by adding in its place ''051311''.

§ 520.446 [Amended]

■ 6. Section 520.446 *Clindamycin capsules and tablets* is amended in paragraph (b)(3) by removing ''059079'' and by adding in its place ''051311''.

§ 520.447 [Amended]

■ 7. Section 520.447 *Clindamycin liquid* is amended in paragraph (b)(2) by removing ''059079'' and by adding in its place ''051311''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 8. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.900 [Amended]

■ 9. Section 522.900 *Euthanasia solution* is amended in paragraph (b)(1) by removing ''059079'' and by adding in its place ''051311''.

Dated: September 15, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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